

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Kenneth Gall, et al.	Examiner:	Jan Christopher Merene
Serial No.:	10/598,080	Group Art Unit:	3733
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Customer No.:	37705	Confirmation No.:	9897
Title:	A GRAFT FIXATION DEVICE AND METHOD		

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APPELLANT'S REPLY BRIEF

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Sir:

This Appellant's Reply Brief is filed under 37 CFR §41.41 in response to the Examiner's Answer mailed June 23, 2011. No fees are believed to be due in conjunction with Appellant's Reply Brief, however consent is granted to charge any additional fees that may be due to Deposit Account 502775.

ARGUMENT

[1] THE EXAMINER'S ANSWER DOES NOT REFUTE APPELLANT'S ASSERTION THAT THE REJECTION OF CLAIM 46 FAILS TO ADDRESS ALL OF THE ELEMENTS AND LIMITATIONS OF CLAIM 46

The Examiner has not refuted Appellant's assertion that the appealed rejections of Claim 46 fail to comply with clear Supreme Court precedent that requires comparing the prior art and the claims. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966); *see also KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 407 (2007) ("the factors continue to define the inquiry that controls"). As set forth in Appellant's Brief, the claims have significant elements that the Examiner has not compared with the prior art, nor has the Examiner set forth the relevant level of ordinary skill. Proving obviousness requires ascertaining the differences between the prior art and the claims, and thus each claim element must be addressed. *KSR*, 550 U.S. at 407. The Examiner's Answer adds little to the rationale in his Final Office Action, and none of the additional rationale addresses the *Graham* factors or the claim limitations missed by the rejections of the Final Office Action.

Failing to require the Examiner to carry his initial burden of providing a proper *prima facie* case of obviousness would improperly and prematurely shift the burden to the Applicant because the *Graham* analysis has not been followed. *In re Kumar*, 418 F.3d 1361, 1366 (Fed. Cir. 2005) (burden shifts only after setting forth a proper obviousness rejection); *see also, In re Piasecki*, 745 F.2d 1468, 1471-72 (Fed. Cir. 1984) (*prima facie* case and rebuttal evidence are procedural mechanisms for orderly allocating burdens). The Board should not accept the Examiner's invitation to ignore the important *Graham* analysis of setting forth the relevant level of ordinary skill and ascertaining the differences between the prior art and the claims.

Because the Examiner has failed to apply the *Graham* factors in his obviousness rejections, Applicant requests reversal of all rejections.

[2] THE EXAMINER FAILS TO SUPPORT HIS ASSERTION OF THE “COMMON KNOWLEDGE”
OR “OFFICIAL NOTICE” OF AN UNKNOWN SHAPE MEMORY POLYMER WITH
“SUFFICIENT STRENGTH TO BE PLACED IN THE BONE”

In his Answer, the Examiner argues for the first time that the “common knowledge in the art” provides “a shape memory polymer with sufficient strength to be placed in the bone” that is sufficient to make the Li device functional for fixing tendon to bone. The Examiner thus (1) further violates the mandate of the proper *Graham* analysis by not assessing the level of skill in the art that would have “common knowledge” of such a shape memory polymer and (2) improperly attempts to enter new grounds for his rejection based on “official notice” regarding the existence of such a shape memory polymer.

First, through the Examiner’s attempts to assert “common knowledge” in carrying his burden of proving obviousness, the Examiner underscores the effects of failing to follow the *Graham* analysis requirement of establishing the level of skill in the art. Without establishing the necessary level of skill in the art, the Examiner’s assertions of “common knowledge” cannot be judged.

Second, the Examiner may only introduce official notice evidence where it is “capable of such instant and unquestionable demonstration as to defy dispute.” *In re Ahlert*, 424 F.2d 1088, 1091 (Fed. Cir. 1970) (court will always construe the breadth of judicial notice narrowly). In the present instance, the Examiner relies on his unsupported belief that a shape memory polymer with “sufficient strength” exists. Such an assertion is legally improper without a citation. *Id.* (“Assertions of technical facts in areas of esoteric technology must always be supported by citation....”); *see also, In re Kaplan*, 789 F.2d 1574, 1580 (Fed. Cir. 1986) (“Even if obviousness of the variation is predicated on the level of skill in the art, prior art evidence is needed to show what that level of skill was”). Particularly where the evidence relates to core factual findings, such as basing obviousness on the properties of an unknown and unnamed shape memory polymer, the officially-noticed evidence must be supported by concrete citation. *In re Zurko*, 258 F.3d 1379, 1385-86 (Fed. Cir. 2001).

Because the Examiner has improperly included new “official notice” evidence about what was “common knowledge in the art” in his modified rejection in his Answer, Applicant requests reversal of the rejections based on Li and Lendlein.

[3] THE EXAMINER’S NEW EVIDENCE CONSTITUTES A NEW GROUND FOR REJECTION

In his Answer, the Examiner relies for the first time on the “common knowledge” of a shape memory polymer with “sufficient strength to be placed in bone” such that the Li device could function to fix tendon to bone. However, identification of values purported to overlap with the prior art is material to a rejection, and, when appearing for the first time during appeal, constitutes a new ground for rejection. *In re Kumar*, 418 F.3d at 1367-68. Had the Examiner properly designated this newly-reformulated rejection as a new ground for rejection in his Answer, the Applicant would have the fair opportunity to respond to the new evidence either on appeal or during examination. 37 CFR §§1.104(d)(2) and 41.39; *see also, In re Ahlert*, 424 F.2d at 1092 (judicial notice is primarily procedural and should be used “while balancing the applicant's rights to fair notice and an opportunity to be heard”).

Because the Examiner has modified his rejections based on Li and Lendlein with new evidence, Applicant requests that the Board designate the Examiner’s modified rejections as “new grounds for rejection” and give Applicant the fair opportunity to rebut the Examiner’s unsupported conclusions.

[4] THE EXAMINER ATTEMPTS TO RE-WRITE DOVESI TO INCLUDE NEW TEACHINGS ABOUT SHAPE CHANGE OF THE DOVESI DEVICE

In his Answer, the Examiner attempts to re-write the Dovesi reference to add a shape changing aspect to the Dovesi device - an aspect that is not taught by Dovesi. As noted in Applicant’s Brief, the Dovesi device has no shape-changing characteristics, nor any description of how the two precisely interlocking elements of Dovesi’s device would operate with shape changes. The Examiner disregards these teachings, and attempts to add hypothetical shape-changes to the Dovesi device. “[T]he device of Dovesi can be implanted as described, where when in place, it can be activated by, for example, heat, the device can be expanded back to a

larger original shape. This allows the device is [sic] able to press further against the bone and enhance fixation of the cable member against the bone.” Examiner’s Answer, p. 12. These statements are the Examiner’s own creation and they are not part of the Dovesi specification.

Because the Examiner has improperly attempted to modify Dovesi in his Answer, Applicant requests reversal of the rejections based on Dovesi and Lendlein.

CONCLUSION

The factors for analysis laid out in *Graham*, as affirmed in *KSR*, are required as a matter of law. In this instance, the Examiner has set forth improper rejections (1) without defining the differences between the prior art and the actual language of the claims, and (2) without setting forth the level of ordinary skill in the art. The Examiner’s rejections are therefore improper as a matter of law.

Furthermore, the Examiner has improperly attempted to add evidence both via improperly adding evidence by “official notice,” and via attempting to re-write Dovesi to include disclosure of a new device.

Reversal of the Examiner’s rejections and allowance of all Claims on appeal are therefore respectfully solicited.

Respectfully submitted,

Date: August 16, 2011

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Included attachments:

Claims Appendix: Claims on Appeal
Evidence Appendix: None
Related Proceedings Appendix: None

APPENDIX A

Claims on Appeal:

1-45. (Cancelled).

46. (Previously presented) A method comprising:

inserting a cable member into a recess in a bone;

inserting a retention device containing a shape memory polymer into the recess while the shape memory polymer is in a temporary pre-implantation shape due to a shape memory effect of the shape memory polymer;

positioning the retention device in the recess while the shape memory polymer is in the temporary pre-implantation shape such that the retention device contacts the cable member and the bone; and

causing the shape memory polymer to change its shape through the shape memory effect from the temporary pre-implantation shape toward an unconstrained shape of the shape memory polymer, thereby fixing the cable member to the bone with the retention device.

47-50. (Cancelled)

51. (Original) The method of claim 46, wherein the cable member is selected from an animal tissue, a synthetic fiber, a natural fiber, a polymer, a metallic wire, a bundle, and a composite.

52. (Original) The method of claim 51, wherein the animal tissue is human soft tissue.

53-54. (Cancelled)

55. (Original) The method of claim 46, wherein the inserting the cable member operation precedes the inserting the retention device operation.

56. (Original) The method of claim 46, wherein the inserting the cable member operation is performed simultaneously with the inserting the retention device operation.

57-138. (Cancelled).

139. (Previously presented) The method of claim 46, wherein causing the shape memory polymer to change shape through the shape memory effect is performed by heating, and wherein the heating comprises a transfer of heat from the bone to the shape memory polymer.

APPENDIX A

140. (Previously presented) The method of claim 46, wherein causing the shape memory polymer to change shape through the shape memory effect is performed by heating, and wherein the heating comprises flooding the retention device with a liquid bath.

141. (Previously presented) The method of claim 46, wherein causing the shape memory polymer to change shape through the shape memory effect is performed by heating, and wherein the heating comprises a transfer of heat from the bone to the shape memory polymer, and flooding the retention device with a liquid bath.